

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Rebecca Gomez
Application No. : 10/696,258 Confirmation No. : 7051
Filed : October 28, 2003
For : APPARATUS FOR TREATING HEMORRHOIDS AND SIMILAR
AILMENTS
Art Unit : 3769
Examiner : David M. Shay

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

DECLARATION UNDER 37 C.f.R. § 1.132 OF RANDOLPH M. STEINHAGEN

Sir:

I, Randolph M. Steinhagen, hereby declare as follows:

1. That I am the Chief of the Division of Colon and Rectal Surgery at Mount Sinai Medical Center located in New York City, New York, and have worked at Mount Sinai Medical Center since 1984. In addition, I have a position as the Professor of Surgery in the Mount Sinai School of Medicine;

2. That I am very familiar with the claimed invention of the above-identified patent application Serial No. 10/696,258 (hereinafter referred to as "the Application"). I

have reviewed the Application and the claims therein which are at issue;

3. That I have moreover worked in a clinical trial to test this claimed invention. The results of this clinical trial indicated that the claimed invention was generally a success and preferred by the subjects of the trial;

4. That I am familiar with the following Rosenberg reference cited by the Examiner, *The Dilemma of Pilonidal Disease: Reverse Bandaging for Cure of the Reluctant Pilonidal Wound* (hereinafter referred to as "Rosenberg") that was published in a 1977 issue of *The Diseases of the Colon and Rectum*. It is my understanding that claims 13, 14, 21, 27, 33, 35-37 and 39 of the Application have been rejected by the Examiner based on Rosenberg;

5. That I have reviewed the Rosenberg publication and have compared the technology described therein to the claimed invention of the Application. Rosenberg describes a "strapping" technique in which an adhesive strapping is strapped to a person's buttocks and crossed in front of the abdomen. This is done to facilitate the healing of a postoperative pilonidal sinus wound;

6. That not only is the adhesive strapping described by Rosenberg applied to a different part of the body than the claimed invention, but the purpose is also different. For example, Rosenberg describes a technique of applying postoperative wound dressings to facilitate the healing of a pilonidal surgical wound. The claimed invention, on the other

hand, includes a unique shape and structure that is designed to reduce inflammation in the anal area and can provide relief of symptomatic hemorrhoids. The claimed invention can also provide further benefits, such as obviating the need for a hemorrhoids patient to undergo surgery;

7. That the claimed invention has a unique shape and structure not shown by Rosenberg. The claimed invention can operate to reduce inflammation by lifting the inflamed tissue at a very specific angle that follows the anatomy of the patient's body. This particular lifting that is provided by the unique shape and structure of the claimed invention can allow the hemorrhoid to return to its normal position, thereby resulting in enhanced healing effects to the inflamed tissue. Moreover, the specific angle at which the claimed invention lifts the inflamed tissue does not hinder movement of a patient's body. The claimed invention can therefore allow a patient to walk, sit, sleep, or otherwise continue their daily life without discomfort, despite the presence of the hemorrhoids condition or the application of the claimed invention. Rosenberg does not describe such a unique shape and structure and therefore does not produce the above-mentioned benefits of the claimed invention;

8. That the above-mentioned differences between Rosenberg and the claimed invention demonstrate the superiority of the claimed invention over Rosenberg;

9. That, in my opinion, the above-mentioned superiority of the claimed invention over Rosenberg, including the differences between the two devices, would not have been

obvious to one skilled in art at the time the Application was filed;

10. That, in my expert opinion, many people could benefit from the claimed invention. The claimed invention can provide benefits such as enhanced healing effects and helping patients avoid surgery, thereby significantly reducing health care costs;

11. That Rosenberg does not show the claimed invention. Nor, to my knowledge, is there any product on the market that is similar to the claimed invention. After comparing Rosenberg with the claimed invention, I have concluded that any supposed similarities between Rosenberg and the claimed invention are minimal at best and negligible;

12. That I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application and any patent issued thereon.

10/28/2009
Date

R. M. Steinhagen
Randolph M. Steinhagen